available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[62 FR 40592, July 29, 1997, as amended at 68 FR 24879, May 9, 2003]

## Subpart F—Other Requirements

### § 25.60 Environmental effects abroad of major agency actions.

(a) In accordance with Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions'' of January 4, 1979 (44 FR 1957, January 9, 1979), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine, in accordance with section 2–3 of the Executive Order, whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine, in accordance with section 2–4 (a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2–5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

# PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

Sec.

### Subpart B—Specific Sector Provisions for Medical Devices



### Subpart C—''Framework'' Provisions



AUTHORITY: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

SOURCE: 63 FR 60141, Nov. 6, 1998, unless otherwise noted.

### § 26.0 General.

This part substantially reflects relevant provisions of the framework agreement and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices of the ''Agreement on Mutual Recognition Between the United States of America and the European Community'' (the MRA), signed at London May 18, 1998. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA concluded between the United States and the European Community (EC), or the rights and obligations of the United States or the EC under that agreement. Whereas the parties to the MRA are the United States and EC, this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA, including the sectoral annexes reflected in subparts A and B of this part. This part does not govern implementation of the MRA by the EC, which will implement the MRA in accordance with its internal procedures, nor does this part address implementation of the MRA by other concerned U.S. Federal agencies. For purposes of this part, the terms ''party'' or ''parties,'' where relevant to FDA's implementation of the MRA, should be considered as referring to FDA only. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly,

using appropriate administrative procedures.

## Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

### § 26.1 Definitions.

(a) *Enforcement* means action taken by an authority to protect the public from products of suspect quality, safety, and effectiveness or to assure that products are manufactured in compliance with appropriate laws, regulations, standards, and commitments made as part of the approval to market a product.

(b) *Equivalence* of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. Equivalence does not require that the respective regulatory systems have identical procedures.

(c) *Good Manufacturing Practices* (GMP's). [The United States has clarified its interpretation that under the MRA, paragraph (c)(1) of this section has to be understood as the U.S. definition and paragraph (c)(2) as the EC definition.]

(1) GMP's mean the requirements found in the legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification in the EC).

(d) *Inspection* means an onsite evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP's and/or commitments made as part of the approval to market a product.

(e) *Inspection report* means the written observations and GMP's compliance assessment completed by an authority listed in Appendix B of this subpart.

(f) *Regulatory system* means the body of legal requirements for GMP's, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

### § 26.2 Purpose.

The provisions of this subpart govern the exchange between the parties and normal endorsement by the receiving regulatory authority of official good manufacturing practices (GMP's) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the parties, which is the cornerstone of this subpart.

### § 26.3 Scope.

(a) The provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community (EC) before products are marketed (hereafter referred to as ''preapproval inspections'') as well as during their marketing (hereafter referred to as ''postapproval inspections'').

(b) Appendix A of this subpart names the laws, regulations, and administrative provisions governing these inspections and the good manufacturing practices (GMP's) requirements.

(c) Appendix B of this subpart lists the authorities participating in activities under this subpart.

(d) Sections 26.65, 26.66, 26.67, 26.68, 26.69, and 26.70 of subpart C of this part do not apply to this subpart.

### § 26.4 Product coverage.

(a) The provisions of this subpart will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the European Community (EC)) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both parties as listed in Appendix B of this subpart.

(b) Human blood, human plasma, human tissues and organs, and veterinary immunologicals (under 9 CFR 101.2, ''veterinary immunologicals'' are referred to as ''veterinary biologicals'') are excluded from the scope of this subpart. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals, and medicinal gases are also excluded during the transition phase; their situation will be reconsidered at the end of the transition period. Products regulated by the Food and Drug Administration's Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research as devices are not covered under this subpart.

(c) Appendix C of this subpart contains an indicative list of products covered by this subpart.

[63 FR 60141, Nov. 6, 1998, as amended at 70 FR 14980, Mar. 24, 2005]

### § 26.5 Length of transition period.

A 3-year transition period will start immediately after the effective date described in § 26.80(a).

### § 26.6 Equivalence assessment.

(a) The criteria to be used by the parties to assess equivalence are listed in Appendix D of this subpart. Information pertaining to the criteria under European Community (EC) competence will be provided by the EC.

(b) The authorities of the parties will establish and communicate to each other their draft programs for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programs will be carried out, as deemed necessary by the regulatory authorities, for post- and preapproval inspections and for various product classes or processes.

(c) The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the parties will ensure that efforts are made to save resources.

(d) Equivalence assessment for authorities added to Appendix B of this subpart after the effective date described in § 26.80(a) will be conducted as described in this subpart, as soon as practicable.

### § 26.7 Participation in the equivalence assessment and determination.

The authorities listed in Appendix B of this subpart will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

### § 26.8 Other transition activities.

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

### § 26.9 Equivalence determination.

(a) Equivalence is established by having in place regulatory systems covering the criteria referred to in Appendix D of this subpart, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g., postapproval or preapproval) or product classes or processes.

(b) The parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of nonequivalence, in sufficient detail to allow the authority

being assessed to know how to attain equivalence.

### § 26.10 Regulatory authorities not listed as currently equivalent.

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

### § 26.11 Start of operational period.

(a) The operational period shall start at the end of the transition period and its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

(b) In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in § 26.12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the parties will agree on procedures for exercising this option.

(c) In the European Community (EC), the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC (see Appendix A of this subpart) provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the World Health Organization Certification Scheme on the Quality of Medicinal Products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

### § 26.12 Nature of recognition of inspection reports.

(a) Inspection reports (containing information as established under § 26.8), including a good manufacturing practice (GMP) compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing party may request clarification from the authority of the exporting party which may lead to a request for reinspection. The authorities will endeavor to respond to requests for clarification in a timely manner.

(b) Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

### § 26.13 Transmission of postapproval inspection reports.

Postapproval good manufacturing practice (GMP) inspection reports concerning products covered by this subpart will be transmitted to the authority of the importing country within 60-calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90-calendar days of the request.

### § 26.14 Transmission of preapproval inspection reports.

(a) A preliminary notification that an inspection may have to take place will be made as soon as possible.

(b) Within 15-calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the European Community (EC), requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of

Medicinal Products (EMEA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

(c) Reports of preapproval inspections will be sent within 45-calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

### § 26.15 Monitoring continued equivalence.

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections; and the conduct of common training sessions.

### § 26.16 Suspension.

(a) Each party has the right to contest the equivalence of a regulatory authority. This right will be exercised in an objective and reasoned manner in writing to the other party.

(b) The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the Joint Sectoral Committee determines that verification of equivalence is required, it may be carried out jointly by the parties in a timely manner, under § 26.6.

(c) Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee as described in § 26.73. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

(d) Upon the suspension of authority previously listed as equivalent, a party is no longer obligated to normally endorse the inspection reports of the suspended authority. A party shall continue to normally endorse the inspection reports of that authority prior to suspension, unless the authority of the receiving party decides otherwise based on health or safety considerations. The suspension will remain in effect until unanimous consent has been reached by the parties on the future status of that authority.

### § 26.17 Role and composition of the Joint Sectoral Committee.

(a) A Joint Sectoral Committee is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who each will have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment, which must be agreed by both parties, of the equivalence of the respective authorities;

(2) Developing and maintaining the list of equivalent authorities, including any limitation in terms of inspecting type or products, and communicating the list to all authorities and the Joint Committee;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that an authority may be no longer equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

(d) The Joint Sectoral Committee shall meet at the request of either party and, unless the cochairs otherwise agree, at least once each year. The Joint Committee will be kept informed of the agenda and conclusions of meetings of the Joint Sectoral Committee.

### § 26.18 Regulatory collaboration.

(a) The parties and authorities shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix B of this subpart.

### § 26.19 Information relating to quality aspects.

The authorities will establish an appropriate means of exchanging information on any confirmed problem reports, corrective actions, recalls, rejected import consignments, and other regulatory and enforcement problems for products subject to this subpart.

### § 26.20 Alert system.

(a) The details of an alert system will be developed during the transitional period. The system will be maintained in place at all times. Elements to be considered in developing such a system are described in Appendix E of this subpart.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, recalls, counterfeiting, and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

### § 26.21 Safeguard clause.

Each party recognizes that the importing country has a right to fulfill its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. This includes the suspension of the distribution, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in § 26.12.

## APPENDIX A TO SUBPART A OF PART 26—LIST OF APPLICABLE LAWS, REGULATIONS, AND ADMINISTRATIVE PROVISIONS

1. For the European Community (EC):

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036. EC documents may be viewed on the European Commission Pharmaceuticals Units web site at http://dg3.eudra.org.]

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products as extended, widened, and amended.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation EEC No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use.

Guide to Good Distribution Practice (94/C 63/03).

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV.

2. For the United States:

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents, except the FDA Compliance Program Guidance Manual, may be viewed on FDA's Internet web site at http://www.FDA.gov.]

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act.

Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1–99, Parts 200–299, Parts 500–599, and Parts 600–799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

## APPENDIX B TO SUBPART A OF PART 26—LIST OF AUTHORITIES

1. For the United States: In the United States, the regulatory authority is the Food and Drug Administration.

2. For the European Community: In the European Community, the regulatory authorities are the following:

Belgium: Inspection générale de la Pharmacie, Algemene Farmaceutische Inspectie.
Denmark: Laegemiddelstyrelsen.
Germany: Bundesministerium für Gesundheit for immunologicals: Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines.
Greece: Εθνικως Ωργανισμως Φαρμακων, Ministry of Health and Welfare, National Drug Organization (E.O.F).
Spain: For medicinal products for human use: Ministerio de Sanidad y Consumo, Subdirección General de Control Farmacéutico. For medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA), Dirección General de la Producción Agraria.
France: For medicinal products for human use: Agence du Médicament. For veterinary medicinal products: Agence Nationale du Médicament Vétérinaire.
Ireland: Irish Medicines Board.
Italy: For medicinal products for human use: Ministero della Sanità, Dipartimento Farmaci e Farmacovigilanza. For medicinal products for veterinary use: Ministero della Sanità, Dipartimento alimenti e nutrizione e sanità pubblica veterinaria-Div. IX.
Luxembourg: Division de la Pharmacie et des Médicaments.
Netherlands: Staat der Nederlanden.
Austria: Bundesministerium für Arbeit, Gesundheit und Soziales.
Portugal: Instituto da Farmácia e do Medicamento (INFARMED).
Finland: Lääkelaitos/Läkemedelsverket (National Agency for Medicines).
Sweden: Läkemedelsverket-Medical Products Agency.
United Kingdom: For human use and veterinary (non-immunologicals): Medicines Control Agency. For veterinary immunologicals: Veterinary Medicines Directorate.
European Community: Commission of the European Communities. European Agency for the Evaluation of Medicinal Products (EMEA).

## APPENDIX C TO SUBPART A OF PART 26—INDICATIVE LIST OF PRODUCTS COVERED BY SUBPART A

Recognizing that precise definition of medicinal products and drugs are to be found in the legislation referred to above, an indicative list of products covered by this arrangement is given below:

—human medicinal products including prescription and nonprescription drugs;
—human biologicals including vaccines, and immunologicals;
—veterinary pharmaceuticals, including prescription and nonprescription drugs, with the exclusion of veterinary immunologicals (Under 9 CFR 101.2 ''veterinary immunologicals'' are referred to as ''veterinary biologicals'');
—premixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (United States);
—intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (United States)/starting materials (EC).

## APPENDIX D TO SUBPART A OF PART 26—CRITERIA FOR ASSESSING EQUIVALENCE FOR POST- AND PREAPPROVAL

I. Legal/Regulatory authority and structures and procedures providing for post- and preapproval:

A. Appropriate statutory mandate and jurisdiction.
B. Ability to issue and update binding requirements on GMP's and guidance documents.
C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.
D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.
E. Substantive current good manufacturing requirements.
F. Accountability of the regulatory authority.
G. Inventory of current products and manufacturers.
H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by subpart A of this part.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

A. Standards of education/qualification and training.
B. Effective quality assurance systems measures to ensure adequate job performance.
C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of inspections:

A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective use of surveillance systems:

A. Sampling and analysis.
B. Recall monitoring.
C. Product defect reporting system.
D. Routine surveillance inspections.
E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

VII. Additional specific criteria for preapproval inspections:

A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the regulatory authorities' capabilities.
B. Preinspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.
C. Ability to verify chemistry, manufacturing, and control data supporting an application is authentic and complete.
D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.
E. Ability to verify conformity of the onsite processes and procedures with those described in the application.
F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

APPENDIX E TO SUBPART A OF PART 26—ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO-WAY ALERT SYSTEM

1. Documentation

—Definition of a crisis/emergency and under what circumstances an alert is required
—Standard Operating Procedures (SOP's)
—Mechanism of health hazards evaluation and classification
—Language of communication and transmission of information

2. Crisis Management System

—Crisis analysis and communication mechanisms
—Establishment of contact points
—Reporting mechanisms

3. Enforcement Procedures

—Followup mechanisms
—Corrective action procedures

4. Quality Assurance System

—Pharmacovigilance programme
—Surveillance/monitoring of implementation of corrective action

5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44–171–418 8400, Fax 418–8416.

B. For the United States :

Biologics: Director, Office of Compliance and Biologics Quality (HFM–600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301–827–6190, fax: 301–594-1944.
Human Drugs: Director, Office of Compliance (HFD–300), 5600 Fishers Lane, Rockville, MD 20857, phone: 301–827–8910, fax: 301–827–8901.
Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV–200), MPN II, 7500 Standish Pl., Rockville, MD 20855–2773, phone: 301–827–6644, fax: 301–594–1807.

[63 FR 60141, Nov. 6, 1998, as amended at 69 FR 48775, Aug. 11, 2004]

## Subpart B—Specific Sector Provisions for Medical Devices

### § 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality

system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

### § 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the following types of reports from conformity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

### § 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations.* U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation.* U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in Appendix B of this subpart.

(3) *Postmarket Vigilance Reports.* Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(b) Additional products and procedures may be made subject to this subpart by agreement of the parties.

### § 26.34 Regulatory authorities.

The regulatory authorities shall have the responsibility of implementing the provisions of this subpart, including the designation and monitoring of conformity assessment bodies (CAB's). Regulatory authorities will be specified in Appendix C of this subpart. Each party will promptly notify the other party in writing of any change in the regulatory authority for a country.

### § 26.35 Length and purpose of transition period.

There will be a 3-year transition period immediately following the date described in § 26.80(a). During the transition period, the parties will engage in confidence-building activities for the purpose of obtaining sufficient evidence to make determinations concerning the equivalence of conformity assessment bodies (CAB's) of the other party with respect to the ability to perform quality system and product evaluations or other reviews resulting in reports to be exchanged under this subpart.

### § 26.36 Listing of CAB's.

Each party shall designate conformity assessment bodies (CAB's) to participate in confidence building activities by transmitting to the other

party a list of CAB's which meet the criteria for technical competence and independence, as identified in Appendix A of this subpart. The list shall be accompanied by supporting evidence. Designated CAB's will be listed in Appendix D of this subpart for participation in the confidence building activities once confirmed by the importing party. Nonconfirmation would have to be justified based on documented evidence.

### § 26.37 Confidence building activities.

(a) At the beginning of the transitional period, the Joint Sectoral Group will establish a joint confidence building program calculated to provide sufficient evidence of the capabilities of the designated conformity assessment bodies (CAB's) to perform quality system or product evaluations to the specifications of the parties.

(b) The joint confidence building program should include the following actions and activities:

(1) Seminars designed to inform the parties and CAB's about each party's regulatory system, procedures, and requirements;

(2) Workshops designed to provide the parties with information regarding requirements and procedures for the designation and surveillance of CAB's;

(3) Exchange of information about reports prepared during the transition period;

(4) Joint training exercises; and

(5) Observed inspections.

(c) During the transition period, any significant problem that is identified with a CAB may be the subject of cooperative activities, as resources allow and as agreed to by the regulatory authorities, aimed at resolving the problem.

(d) Both parties will exercise good faith efforts to complete the confidence building activities as expeditiously as possible to the extent that the resources of the parties allow.

(e) Both the parties will each prepare annual progress reports which will describe the confidence building activities undertaken during each year of the transition period. The form and content of the reports will be determined by the parties through the Joint Sectoral Committee.

### § 26.38 Other transition period activities.

(a) During the transition period, the parties will jointly determine the necessary information which must be present in quality system and product evaluation reports.

(b) The parties will jointly develop a notification and alert system to be used in case of defects, recalls, and other problems concerning product quality that could necessitate additional actions (e.g., inspections by the parties of the importing country) or suspension of the distribution of the product.

### § 26.39 Equivalence assessment.

(a) In the final 6 months of the transition period, the parties shall proceed to a joint assessment of the equivalence of the conformity assessment bodies (CAB's) that participated in the confidence building activities. CAB's will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CAB's may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this subpart and with regard to any type of product covered by this subpart. The parties shall develop a list contained in Appendix E of this subpart of CAB's determined to be equivalent, which shall contain a full explanation of the scope of the equivalency determination, including any appropriate limitations, with regard to performing any type of quality system or product evaluation.

(b) The parties shall allow CAB's not listed for participation in this subpart, or listed for participation only as to certain types of evaluations, to apply for participation in this subpart once the necessary measures have been taken or sufficient experience has been gained, in accordance with § 26.46.

(c) Decisions concerning the equivalence of CAB's must be agreed to by both parties.

### § 26.40 Start of the operational period.

(a) The operational period will start at the end of the transition period after the parties have developed the list of conformity assessment bodies (CAB's)

found to be equivalent. The provisions of §§ 26.40, 26.41, 26.42, 26.43, 26.44, 26.45, and 26.46 will apply only with regard to listed CAB's and only to the extent of any specifications and limitations contained on the list with regard to a CAB.

(b) The operational period will apply to quality system evaluation reports and product evaluation reports generated by CAB's listed in accordance with this subpart for the evaluations performed in the respective territories of the parties, except if the parties agree otherwise.

### § 26.41 Exchange and endorsement of quality system evaluation reports.

(a) Listed European Community (EC) conformity assessment bodies (CAB's) will provide FDA with reports of quality system evaluations, as follows:

(1) For preapproval quality system evaluations, EC CAB's will provide full reports; and

(2) For surveillance quality system evaluations, EC CAB's will provide abbreviated reports.

(b) Listed U.S. CAB's will provide to the EC Notified Body of the manufacturer's choice:

(1) Full reports of initial quality system evaluations;

(2) Abbreviated reports of quality systems surveillance audits.

(c) If the abbreviated reports do not provide sufficient information, the importing party may request additional clarification from the CAB.

(d) Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in a report, quality defects identified in postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the importing party may request clarification from the exporting party which may lead to a request for reinspection. The parties will endeavor to respond to requests for clarification in a timely manner. Where divergence is not clarified in this process, the importing party may carry out the quality system evaluation.

### § 26.42 Exchange and endorsement of product evaluation reports.

(a) European Community (EC) conformity assessment bodies (CAB's) listed for this purpose will, subject to the specifications and limitations on the list, provide to FDA 510(k) premarket notification assessment reports prepared to U.S. medical device requirements.

(b) U.S. CAB's will, subject to the specifications and limitations on the list, provide to the EC Notified Body of the manufacturer's choice, type examination, and verification reports prepared to EC medical device requirements.

(c) Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing party may request clarification from the exporting party which may lead to a request for a reevaluation. The parties will endeavor to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing party.

### § 26.43 Transmission of quality system evaluation reports.

Quality system evaluation reports covered by § 26.41 concerning products covered by this subpart shall be transmitted to the importing party within 60-calendar days of a request by the importing party. Should a new inspection be requested, the time period shall be extended by an additional 30-calendar days. A party may request a new inspection, for cause, identified to the other party. If the exporting party cannot perform an inspection within a specified period of time, the importing

party may perform an inspection on its own.

### § 26.44 Transmission of product evaluation reports.

Transmission of product evaluation reports will take place according to the importing party's specified procedures.

### § 26.45 Monitoring continued equivalence.

Monitoring activities will be carried out in accordance with § 26.69.

### § 26.46 Listing of additional CAB's.

(a) During the operational period, additional conformity assessment bodies (CAB's) will be considered for equivalence using the procedures and criteria described in §§ 26.36, 26.37, and 26.39, taking into account the level of confidence gained in the overall regulatory system of the other party.

(b) Once a designating authority considers that such CAB's, having undergone the procedures of §§ 26.36, 26.37, and 26.39, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of § 26.66(a) and (b).

(c) Following such annual designations, the procedures for confirmation of CAB's under § 26.66(c) and (d) shall apply.

### § 26.47 Role and composition of the Joint Sectoral Committee.

(a) The Joint Sectoral Committee for this subpart is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who will each have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment of the equivalence of conformity assessment bodies (CAB's);

(2) Developing and maintaining the list of equivalent CAB's, including any limitation in terms of their scope of activities and communicating the list to all authorities and the Joint Committee described in subpart C of this part;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

### § 26.48 Harmonization.

During both the transitional and operational phases of this subpart, both parties intend to continue to participate in the activities of the Global Harmonization Task Force (GHTF) and utilize the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the GHTF and jointly determining whether they are applicable to the implementation of this subpart.

### § 26.49 Regulatory cooperation.

(a) The parties and authorities shall inform and consult with one another, as permitted by law, of proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix A of this subpart.

### § 26.50 Alert system and exchange of postmarket vigilance reports.

(a) An alert system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an Appendix F of this subpart. As part of that system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which

could necessitate additional controls or suspension of the distribution of the product.

## APPENDIX A TO SUBPART B OF PART 26—RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

1. For the European Community (EC) the following legislation applies to §26.42(a) of this subpart:

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.]

a. Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices
OJ No. L 189, 20.7. 1990, p. 17. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 4
Annex 5

b. Council Directive 93/42/EEC of 14 June 1993 on Medical Devices OJ No. L 169,12.7.1993, p.1. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 3
Annex 4
Annex 5
Annex 6

2. For the United States, the following legislation applies to §26.32(a):

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents may be viewed on FDA's Internet web site at http://www.fda.gov.]

a. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq*.

b. The Public Health Service Act, 42 U.S.C. 201 *et seq*.

c. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, Parts 800 to 1299.

d. Medical Devices; Third Party Review of Selected Premarket Notifications; Pilot Program, 61 FR 14789–14796 (April 3, 1996).

e. Draft Guidance Document on Accredited Persons Program, 63 FR 28392 (May 22, 1998).

f. Draft Guidance for Staff, Industry and Third Parties, Third Party Programs under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA), 63 FR 36240 (July 2, 1998).

g. Guidance Document on Use of Standards, 63 FR 9561 (February 25, 1998).

## APPENDIX B TO SUBPART B OF PART 26—SCOPE OF PRODUCT COVERAGE

1. Initial Coverage of the Transition Period

Upon entry into force of this subpart as described in §26.80 (it is understood that the date of entry into force will not occur prior to June 1, 1998, unless the parties decide otherwise), products qualifying for the transitional arrangements under this subpart include:

a. All Class I products requiring premarket evaluations in the United States—see Table 1.

b. Those Class II products listed in Table 2.

2. During the Transition Period

The parties will jointly identify additional product groups, including their related accessories, in line with their respective priorities as follows:

a. Those for which review may be based primarily on written guidance which the parties will use their best efforts to prepare expeditiously; and

b. Those for which review may be based primarily on international standards, in order for the parties to gain the requisite experience.

The corresponding additional product lists will be phased in on an annual basis. The parties may consult with industry and other interested parties in determining which products will be added.

3. Commencement of the Operational Period

a. At the commencement of the operational period, product coverage shall extend to all Class I/II products covered during the transition period.

b. FDA will expand the program to categories of Class II devices as is consistent with the results of the pilot, and with FDA's ability to write guidance documents if the device pilot for the third party review of medical devices is successful. The MRA will cover to the maximum extent feasible all Class II devices listed in Table 3 for which FDA-accredited third party review is available in the United States.

4. Unless explicitly included by joint decision of the parties, this part does not cover any U.S. Class II-tier 3 or any Class III product under either system.

[The lists of medical devices included in these tables are subject to change as a result of the Food and Drug Administration Modernization Act of 1997.]

TABLE 1—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]

| 21 CFR Section No. | Regulation Name |
|---|---|
| | Product Code—Device Name |
| *Anesthesiology Panel (21 CFR Part 868)* | |
| 868.1910 | Esophageal Stethoscope |
| | BZW—Stethoscope, Esophageal |
| 868.5620 | Breathing Mouthpiece |
| | BYP—Mouthpiece, Breathing |
| 868.5640 | Medicinal Nonventilatory Nebulizer (Atomizer) |
| | CCQ—Nebulizer, Medicinal, Nonventilatory (Atomizer) |
| 868.5675 | Rebreathing Device |
| | BYW—Device, Rebreathing |
| 868.5700 | Nonpowered Oxygen Tent |
| | FOG—Hood, Oxygen, Infant |
| | BYL—Tent, Oxygen |
| 868.6810 | Tracheobronchial Suction Catheter |
| | BSY—Catheters, Suction, Tracheobronchial |
| *Cardiovascular Panel* | |
| (None) | |
| *Dental Panel (21 CFR Part 872)* | |
| 872.3400 | Karaya and Sodium Borate With or Without Acacia Denture Adhesive |
| | KOM—Adhesive, Denture, Acacia and Karaya With Sodium Borate |
| 872.3700 | Dental Mercury (U.S.P.) |
| | ELY—Mercury |
| 872.4200 | Dental Handpiece and Accessories |
| | EBW—Controller, Food, Handpiece and Cord |
| | EFB—Handpiece, Air-Powered, Dental |
| | EFA—Handpiece, Belt and/or Gear Driven, Dental |
| | EGS—Handpiece, Contra- and Right-Angle Attachment, Dental |
| | EKX—Handpiece, Direct Drive, AC-Powered |
| | EKY—Handpiece, Water-Powered |
| 872.6640 | Dental Operative Unit and Accessories |
| | EIA—Unit, Operative Dental |
| *Ear, Nose, and Throat Panel (21 CFR Part 874)* | |
| 874.1070 | Short Increment Sensitivity Index (SISI) Adapter |
| | ETR—Adapter, Short Increment Sensitivity Index (SISI) |
| 874.1500 | Gustometer |
| | ETM—Gustometer |
| 874.1800 | Air or Water Caloric Stimulator |
| | KHH—Stimulator, Caloric-Air |
| | ETP—Stimulator, Caloric-Water |
| 874.1925 | Toynbee Diagnostic Tube |
| | ETK—Tube, Toynbee Diagnostic |
| 874.3300 | Hearing Aid |
| | LRB—Face Plate Hearing-Aid |
| | ESD—Hearing-aid, Air-Conduction |
| 874.4100 | Epistaxis Balloon |
| | EMX—Balloon, Epistaxis |
| 874.5300 | ENT Examination and Treatment Unit |
| | ETF—Unit, Examining/Treatment, ENT |
| 874.5550 | Powered Nasal Irrigator |
| | KMA—Irrigator, Powered Nasal |
| 874.5840 | Antistammering Device |
| | KTH—Device, Anti-Stammering |
| *Gastroenterology—Urology Panel (21 CFR Part 876)* | |
| 876.5160 | Urological Clamp for Males |
| | FHA—Clamp, Penile |
| 876.5210 | Enema Kit |
| | FCE—Kit, Enema, (for Cleaning Purpose) |
| 876.5250 | Urine Collector and Accessories |
| | FAQ—Bag, Urine Collection, Leg, for External Use |
| *General Hospital Panel (21 CFR Part 880)* | |
| 880.5270 | Neonatal Eye Pad |
| | FOK—Pad, Neonatal Eye |
| 880.5420 | Pressure Infusor for an I.V. Bag |
| | KZD—Infusor, Pressure, for I.V. Bags |
| 880.5680 | Pediatric Position Holder |
| | FRP—Holder, Infant Position |
| 880.6250 | Patient Examination Glove |
| | LZB—Finger Cot |

TABLE 1—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]—Continued

| 21 CFR Section No. | Regulation Name |
|---|---|
| | Product Code—Device Name |
| | FMC—Glove, Patient Examination |
| | LYY—Glove, Patient Examination, Latex |
| | LZA—Glove, Patient Examination, Poly |
| | LZC—Glove, Patient Examination, Speciality |
| | LYZ—Glove, Patient Examination, Vinyl |
| 880.6375 | Patient Lubricant |
| | KMJ—Lubricant, Patient |
| 880.6760 | Protective Restraint |
| | BRT—Restraint, Patient, Conductive |
| | FMQ—Restraint, Protective |
| *Neurology Panel (21 CFR Part 882)* | |
| 882.1030 | Ataxiagraph |
| | GWW—Ataxiagraph |
| 882.1420 | Electroencephalogram (EEG) Signal Spectrum Analyzer |
| | GWS—Analyzer, Spectrum, Electroencephalogram Signal |
| 882.4060 | Ventricular Cannula |
| | HCD—Cannula, Ventricular |
| 882.4545 | Shunt System Implantation Instrument |
| | GYK—Instrument, Shunt System Implantation |
| 882.4650 | Neurosurgical Suture Needle |
| | HAS—Needle, Neurosurgical Suture |
| 882.4750 | Skull Punch |
| | GXJ—Punch, Skull |
| *Obstetrics and Gynecology Panel* | |
| (None) | |
| *Ophthalmology Panel (21 CFR Part 886)* | |
| 886.1780 | Retinoscope |
| | HKM—Retinoscope, Battery-Powered |
| 886.1940 | Tonometer Sterilizer |
| | HKZ—Sterilizer, Tonometer |
| 886.4070 | Powered Corneal Burr |
| | HQS—Burr, Corneal, AC-Powered |
| | HOG—Burr, Corneal, Battery-Powered |
| | HRG—Engine, Trephine, Accessories, AC-Powered |
| | HFR—Engine, Trephine, Accessories, Battery-Powered |
| | HLD—Engine, Trephine, Accessories, Gas-Powered |
| 886.4370 | Keratome |
| | HNO—Keratome, AC-Powered |
| | HMY—Keratome, Battery-Powered |
| 886.5850 | Sunglasses (Nonprescription) |
| | HQY—Sunglasses (Nonprescription Including Photosensitive) |
| *Orthopedic Panel (21 CFR Part 888)* | |
| 888.1500 | Goniometer |
| | KQX—Goniometer, AC-Powered |
| 888.4150 | Calipers for Clinical Use |
| | KTZ—Caliper |
| *Physical Medicine Panel (21 CFR Part 890)* | |
| 890.3850 | Mechanical Wheelchair |
| | LBE—Stroller, Adaptive |
| | IOR—Wheelchair, Mechanical |
| 890.5180 | Manual Patient Rotation Bed |
| | INY—Bed, Patient Rotation, Manual |
| 890.5710 | Hot or Cold Disposable Pack |
| | IMD—Pack, Hot or Cold, Disposable |
| *Radiology Panel (21 CFR Part 892)* | |
| 892.1100 | Scintillation (Gamma) Camera |
| | IYX—Camera, Scintillation (Gamma) |
| 892.1110 | Positron Camera |
| | IZC—Camera, Positron |
| 892.1300 | Nuclear Rectilinear Scanner |
| | IYW—Scanner, Rectilinear, Nuclear |
| 892.1320 | Nuclear Uptake Probe |
| | IZD—Probe, Uptake, Nuclear |
| 892.1330 | Nuclear Whole Body Scanner |
| | JAM—Scanner, Whole Body, Nuclear |
| 892.1410 | Nuclear Electrocardiograph Synchronizer |
| | IVY—Synchronizer, Electrocardiograph, Nuclear |
| 892.1890 | Radiographic Film Illuminator |
| | IXC—Illuminator, Radiographic-Film |

TABLE 1—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]—Continued

| 21 CFR Section No. | Regulation Name |
|---|---|
| | Product Code—Device Name |
| | JAG—Illuminator, Radiographic-Film, Explosion-Proof |
| 892.1910 | Radiographic Grid |
| | IXJ—Grid, Radiographic |
| 892.1960 | Radiographic Intensifying Screen |
| | EAM—Screen, Intensifying, Radiographic |
| 892.1970 | Radiographic ECG/Respirator Synchronizer |
| | IXO—Synchronizer, ECG/Respirator, Radiographic |
| 892.5650 | Manual Radionuclide Applicator System |
| | IWG—System, Applicator, Radionuclide, Manual |
| *General and Plastic Surgery Panel (21 CFR Part 878)* | |
| 878.4200 | Introduction/Drainage Catheter and Accessories |
| | KGZ—Accessories, Catheter |
| | GCE—Adaptor, Catheter |
| | FGY—Cannula, Injection |
| | GBA—Catheter, Balloon Type |
| | GBZ—Catheter, Cholangiography |
| | GBQ—Catheter, Continuous Irrigation |
| | GBY—Catheter, Eustachian, General & Plastic Surgery |
| | JCY—Catheter, Infusion |
| | GBX—Catheter, Irrigation |
| | GBP—Catheter, Multiple Lumen |
| | GBO—Catheter, Nephrostomy, General & Plastic Surgery |
| | GBN—Catheter, Pediatric, General & Plastic Surgery |
| | GBW—Catheter, Peritoneal |
| | GBS—Catheter, Ventricular, General & Plastic Surgery |
| | GCD—Connector, Catheter |
| | GCC—Dilator, Catheter |
| | GCB—Needle, Catheter |
| 878.4320 | Removable Skin Clip |
| | FZQ—Clip, Removable (Skin) |
| 878.4460 | Surgeon's Gloves |
| | KGO—Surgeon's Gloves |
| 878.4680 | Nonpowered, Single Patient, Portable Suction Apparatus |
| | GCY—Apparatus, Suction, Single Patient Use, Portable, Nonpowered |
| 878.4760 | Removable Skin Staple |
| | GDT—Staple, Removable (Skin) |
| 878.4820 | AC-Powered, Battery-Powered, and Pneumatically Powered Surgical Instrument Motors and Accessories/Attachments |
| | GFG—Bit, Surgical |
| | GFA—Blade, Saw, General & Plastic Surgery |
| | DWH—Blade, Saw, Surgical, Cardiovascular |
| | BRZ—Board, Arm (With Cover) |
| | GFE—Brush, Dermabrasion |
| | GFF—Bur, Surgical, General & Plastic Surgery |
| | KDG—Chisel (Osteotome) |
| | GFD—Dermatome |
| | GFC—Driver, Surgical, Pin |
| | GFB—Head, Surgical, Hammer |
| | GEY—Motor, Surgical Instrument, AC-Powered |
| | GET—Motor, Surgical Instrument, Pneumatic Powered |
| | DWI—Saw, Electrically Powered |
| | KFK—Saw, Pneumatically Powered |
| | HAB—Saw, Powered, and Accessories |
| 878.4960 | Air or AC-Powered Operating Table and Air or AC-Powered Operating Chair & Accessories |
| | GBB—Chair, Surgical, AC-Powered |
| | FQO—Table, Operating-Room, AC-Powered |
| | GDC—Table, Operating-Room, Electrical |
| | FWW—Table, Operating-Room, Pneumatic |
| | JEA—Table, Surgical with Orthopedic Accessories, AC-Powered |
| 880.5090 | Liquid Bandage |
| | KMF—Bandage, Liquid |

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at http://www.fda.gov/cdrh/prodcode.html.

TABLE 2—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS)[1]

| Panel | 21 CFR Section No. | Regulation Name |
|---|---|---|
| | | Product Code—Device Name |
| RA | 892.1000 | Magnetic Resonance Diagnostic Device<br>MOS—COIL, Magnetic Resonance, Specialty<br>LNH—System, Nuclear Magnetic Resonance Imaging<br>LNI—System, Nuclear Magnetic Resonance Spectroscopic |
| Diagnostic Ultrasound: | | |
| RA | 892.1540 | Nonfetal Ultrasonic Monitor<br>JAF—Monitor, Ultrasonic, Nonfetal |
| RA | 892.1550 | Ultrasonic Pulsed Doppler Imaging System<br>IYN—System, Imaging, Pulsed Doppler, Ultrasonic |
| RA | 892.1560 | Ultrasonic Pulsed Echo Imaging System<br>IYO—System, Imaging, Pulsed Echo, Ultrasonic |
| RA | 892.1570 | Diagnostic Ultrasonic Transducer<br>ITX—Transducer, Ultrasonic, Diagnostic |
| Diagnostic X-Ray Imaging Devices (except mammographic x-ray systems): | | |
| RA | 892.1600 | Angiographic X-Ray System<br>IZI—System, X-Ray, Angiographic |
| RA | 892.1650 | Image-Intensified Fluoroscopic X-Ray System<br>MQB—Solid State X-Ray Imager (Flat Panel/Digital Imager)<br>JAA—System, X-Ray, Fluoroscopic, Image-Intensified |
| RA | 892.1680 | Stationary X-Ray System<br>KPR—System, X-Ray, Stationary |
| RA | 892.1720 | Mobile X-Ray System<br>IZL—System, X-Ray, Mobile |
| RA | 892.1740 | Tomographic X-Ray System<br>IZF—System, X-Ray, Tomographic |
| RA | 892.1750 | Computed Tomography X-Ray System<br>JAK—System, X-Ray, Tomography, Computed |
| ECG-Related Devices: | | |
| CV | 870.2340 | Electrocardiograph<br>DPS—Electrocardiograph<br>MLC—Monitor, ST Segment |
| CV | 870.2350 | Electrocardiograph Lead Switching Adaptor<br>DRW—Adaptor, Lead Switching, Electrocardiograph |
| CV | 870.2360 | Electrocardiograph Electrode<br>DRX—Electrode, Electrocardiograph |
| CV | 870.2370 | Electrocardiograph Surface Electrode Tester<br>KRC—Tester, Electrode, Surface, Electrocardiographic |
| NE | 882.1400 | Electroencephalograph<br>GWQ—Electroencephalograph |
| HO | 880.5725 | Infusion Pump (external only)<br>MRZ—Accessories, Pump, Infusion<br>FRN—Pump, Infusion<br>LZF—Pump, Infusion, Analytical Sampling<br>MEB—Pump, Infusion, Elastomeric<br>LZH—Pump, Infusion, Enteral<br>MHD—Pump, Infusion, Gallstone Dissolution<br>LZG—Pump, Infusion, Insulin<br>MEA—Pump, Infusion, PCA |
| Ophthalmic Instruments: | | |
| OP | 886.1570 | Ophthalmoscope<br>HLI—Ophthalmoscope, AC-Powered<br>HLJ—Ophthalmoscope, Battery-Powered |
| OP | 886.1780 | Retinoscope<br>HKL—Retinoscope, AC-Powered |
| OP | 886.1850 | AC-Powered Slit-Lamp Biomicroscope<br>HJO—Biomicroscope, Slit-Lamp, AC-Powered |
| OP | 886.4150 | Vitreous Aspiration and Cutting Instrument<br>MMC—Dilator, Expansive Iris (Accessory)<br>HQE—Instrument, Vitreous Aspiration and Cutting, AC-Powered<br>HKP—Instrument, Vitreous Aspiration and Cutting, Battery-Powered<br>MLZ—Vitrectomy, Instrument Cutter |
| OP | 886.4670 | Phacofragmentation System<br>HQC—Unit, Phacofragmentation |

TABLE 2—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS)[1]—Continued

| Panel | 21 CFR Section No. | Regulation Name |
|---|---|---|
| | | Product Code—Device Name |
| SU | 878.4580 | Surgical Lamp |
| | | HBI—Illuminator, Fiberoptic, Surgical Field |
| | | FTF—Illuminator, Nonremote |
| | | FTG—Illuminator, Remote |
| | | HJE—Lamp, Fluorescein, AC-Powered |
| | | FQP—Lamp, Operating-Room |
| | | FTD—Lamp, Surgical |
| | | GBC—Lamp, Surgical, Incandescent |
| | | FTA—Light, Surgical, Accessories |
| | | FSZ—Light, Surgical, Carrier |
| | | FSY—Light, Surgical, Ceiling Mounted |
| | | FSX—Light, Surgical, Connector |
| | | FSW—Light, Surgical, Endoscopic |
| | | FST—Light, Surgical, Fiberoptic |
| | | FSS—Light, Surgical, Floor Standing |
| | | FSQ—Light, Surgical, Instrument |
| NE | 882.5890 | Transcutaneous Electrical Nerve Stimulator for Pain Relief |
| | | GZJ—Stimulator, Nerve, Transcutaneous, For Pain Relief |
| | | Noninvasive Blood Pressure Measurement Devices: |
| CV | 870.1120 | Blood Pressure Cuff |
| | | DXQ—Cuff, Blood-Pressure |
| CV | 870.1130 | Noninvasive Blood Pressure Measurement System (except nonoscillometric) |
| | | DXN—System, Measurement, Blood-Pressure, Noninvasive |
| HO | 880.6880 | Steam Sterilizer (greater than 2 cubic feet) |
| | | FLE—Sterilizer, Steam |
| Clinical Thermometers: | | |
| HO | 880.2910 | Clinical Electronic Thermometer (except tympanic or pacifier) |
| | | FLL—Thermometer, Electronic, Clinical |
| AN | 868.5630 | Nebulizer |
| | | CAF—Nebulizer (Direct Patient Interface) |
| Hypodermic Needles and Syringes (except antistick and self-destruct): | | |
| HO | 880.5570 | Hypodermic Single Lumen Needle |
| | | MMK—Container, Sharpes |
| | | FMI—Needle, Hypodermic, Single Lumen |
| | | MHC—Port, Intraosseous, Implanted |
| HO | 880.5860 | Piston Syringe |
| | | FMF—Syringe, Piston |
| Selected Dental Materials: | | |
| DE | 872.3060 | Gold-Based Alloys and Precious Metal Alloys for Clinical Use |
| | | EJT—Alloy, Gold Based, For Clinical Use |
| | | EJS—Alloy, Precious Metal, For Clinical Use |
| DE | 872.3200 | Resin Tooth Bonding Agent |
| | | KLE—Agent, Tooth Bonding, Resin |
| DE | 872.3275 | Dental Cement |
| | | EMA—Cement, Dental |
| | | EMB—Zinc Oxide Eugenol |
| DE | 872.3660 | Impression Material |
| | | ELW—Material, Impression |
| DE | 872.3690 | Tooth Shade Resin Material |
| | | EBF—Material, Tooth Shade, Resin |
| DE | 872.3710 | Base Metal Alloy |
| | | EJH—Metal, Base |
| Latex Condoms: | | |
| OB | 884.5300 | Condom |
| | | HIS—Condom |

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at http://www.fda.gov/cdrh/prodcode.html.

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| *Anesthesiology Panel* | | | |
| Anesthesia Devices | 868.5160 | Gas machine for anesthesia or analgesia | 2 |
| | 868.5270 | Breathing system heater | 2 |
| | 868.5440 | Portable oxygen generator | 2 |
| | 868.5450 | Respiratory gas humidifier | 2 |
| | 868.5630 | Nebulizer | 2 |
| | 868.5710 | Electrically powered oxygen tent | 2 |
| | 868.5880 | Anesthetic vaporizer | 2 |
| Gas Analyser | 868.1040 | Powered Algesimeter | 2 |
| | 868.1075 | Argon gas analyzer | 2 |
| | 868.1400 | Carbon dioxide gas analyzer | 2 |
| | 868.1430 | Carbon monoxide gas analyzer | 2 |
| | 868.1500 | Enflurane gas analyzer | 2 |
| | 868.1620 | Halothane gas analyzer | 2 |
| | 868.1640 | Helium gas analyzer | 2 |
| | 868.1670 | Neon gas analyzer | 2 |
| | 868.1690 | Nitrogen gas analyzer | 2 |
| | 868.1700 | Nitrous oxide gas analyzer | 2 |
| | 868.1720 | Oxygen gas analyzer | 2 |
| | 868.1730 | Oxygen uptake computer | 2 |
| Peripheral Nerve Stimulators | 868.2775 | Electrical peripheral nerve stimulator | 2 |
| Respiratory Monitoring | 868.1750 | Pressure plethysmograph | 2 |
| | 868.1760 | Volume plethysmograph | 2 |
| | 868.1780 | Inspiratory airway pressure meter | 2 |
| | 868.1800 | Rhinoanemometer | 2 |
| | 868.1840 | Diagnostic spirometer | 2 |
| | 868.1850 | Monitoring spirometer | 2 |
| | 868.1860 | Peak-flow meter for spirometry | 2 |
| | 868.1880 | Pulmonary-function data calculator | 2 |
| | 868.1890 | Predictive pulmonary-function value calculator | 2 |
| | 868.1900 | Diagnostic pulmonary-function interpretation calculator | 2 |
| | 868.2025 | Ultrasonic air embolism monitor | 2 |
| | 868.2375 | Breathing frequency monitor (except apnea detectors) | 2 |
| | 868.2480 | Cutaneous carbon dioxide ($PcCO_2$) monitor | 2 |
| | 868.2500 | Cutaneous oxygen monitor (for an infant not under gas anesthesia) | 2 |
| | 868.2550 | Pneumotachomometer | 2 |
| | 868.2600 | Airway pressure monitor | 2 |
| | 868.5665 | Powered percussor | 2 |
| | 868.5690 | Incentive spirometer | 2 |
| Ventilator | 868.5905 | Noncontinuous ventilator (IPPB) | 2 |
| | 868.5925 | Powered emergency ventilator | 2 |
| | 868.5935 | External negative pressure ventilator | 2 |
| | 868.5895 | Continuous ventilator | 2 |
| | 868.5955 | Intermittent mandatory ventilation attachment | 2 |
| | 868.6250 | Portable air compressor | 2 |
| *Cardiovascular Panel* | | | |
| Cardiovascular Diagnostic | 870.1425 | Programmable diagnostic computer | 2 |
| | 870.1450 | Densitometer | 2 |
| | 870.2310 | Apex cardiograph (vibrocardiograph) | 2 |
| | 870.2320 | Ballistocardiograph | 2 |
| | 870.2340 | Electrocardiograph | 2 |

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 870.2350 | Electrocardiograph lead switching adaptor | 1 |
| | 870.2360 | Electrocardiograph electrode | 2 |
| | 870.2370 | Electrocardiograph surface electrode tester | 2 |
| | 870.2400 | Vectorcardiograph | 1 |
| | 870.2450 | Medical cathode-ray tube display | 1 |
| | 870.2675 | Oscillometer | 2 |
| | 870.2840 | Apex cardiographic transducer | 2 |
| | 870.2860 | Heart sound transducer | 2 |
| Cardiovascular Monitoring | | Valve, pressure relief, cardiopulmonary bypass | |
| | 870.1100 | Blood pressure alarm | 2 |
| | 870.1110 | Blood pressure computer | 2 |
| | 870.1120 | Blood pressure cuff | 2 |
| | 870.1130 | Noninvasive blood pressure measurement system | 2 |
| | 870.1140 | Venous blood pressure manometer | 2 |
| | 870.1220 | Electrode recording catheter or electrode recording probe | 2 |
| | 870.1270 | Intracavitary phonocatheter system | 2 |
| | 870.1875 | Stethoscope (electronic) | 2 |
| | 870.2050 | Biopotential amplifier and signal conditioner | 2 |
| | 870.2060 | Transducer signal amplifier and conditioner | 2 |
| | 870.2100 | Cardiovascular blood flowmeter | 2 |
| | 870.2120 | Extravascular blood flow probe | 2 |
| | 870.2300 | Cardiac monitor (including cardiotachometer and rate alarm) | 2 |
| | 870.2700 | Oximeter | 2 |
| | 870.2710 | Ear oximeter | 2 |
| | 870.2750 | Impedance phlebograph | 2 |
| | 870.2770 | Impedance plethysmograph | 2 |
| | 870.2780 | Hydraulic, pneumatic, or photoelectric plethysmographs | 2 |
| | 870.2850 | Extravascular blood pressure transducer | 2 |
| | 870.2870 | Catheter tip pressure transducer | 2 |
| | 870.2880 | Ultrasonic transducer | 2 |
| | 870.2890 | Vessel occlusion transducer | 2 |
| | 870.2900 | Patient transducer and electrode cable (including connector) | 2 |
| | 870.2910 | Radiofrequency physiological signal transmitter and receiver | 2 |
| | 870.2920 | Telephone electrocardiograph transmitter and receiver | 2 |
| | 870.4205 | Cardiopulmonary bypass bubble detector | 2 |
| | 870.4220 | Cardiopulmonary bypass heart-lung machine console | 2 |
| | 870.4240 | Cardiovascular bypass heat exchanger | 2 |
| | 870.4250 | Cardiopulmonary bypass temperature controller | 2 |
| | 870.4300 | Cardiopulmonary bypass gas control unit | 2 |
| | 870.4310 | Cardiopulmonary bypass coronary pressure gauge | 2 |
| | 870.4330 | Cardiopulmonary bypass online blood gas monitor | 2 |

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 870.4340 | Cardiopulmonary bypass level sensing monitor and/or control | 2 |
| | 870.4370 | Roller-type cardiopulmonary bypass blood pump | 2 |
| | 870.4380 | Cardiopulmonary bypass pump speed control | 2 |
| | 870.4410 | Cardiopulmonary bypass in-line blood gas sensor | 2 |
| Cardiovascular Therapeutic | 870.5050 | Patient care suction apparatus | 2 |
| | 870.5900 | Thermal regulation system | 2 |
| Defibrillator | 870.5300 | DC-defibrillator (including paddles) | 2 |
| | 870.5325 | Defibrillator tester | 2 |
| Echocardiograph | 870.2330 | Echocardiograph | 2 |
| Pacemaker & Accessories | 870.1750 | External programmable pacemaker pulse generator | 2 |
| | 870.3630 | Pacemaker generator function analyzer | 2 |
| | 870.3640 | Indirect pacemaker generator function analyzer | 2 |
| | 870.3720 | Pacemaker electrode function tester | 2 |
| Miscellaneous | 870.1800 | Withdrawal-infusion pump | 2 |
| | 870.2800 | Medical magnetic tape recorder | 2 |
| | None | Batteries, rechargeable, class II devices | |
| *Dental Panel* | | | |
| Dental Equipment | 872.1720 | Pulp tester | 2 |
| | 872.1740 | Caries detection device | 2 |
| | 872.4120 | Bone cutting instrument and accessories | 2 |
| | 872.4465 | Gas-powered jet injector | 2 |
| | 872.4475 | Spring-powered jet injector | 2 |
| | 872.4600 | Intraoral ligature and wire lock | 2 |
| | 872.4840 | Rotary scaler | 2 |
| | 872.4850 | Ultrasonic scaler | 2 |
| | 872.4920 | Dental electrosurgical unit and accessories | 2 |
| | 872.6070 | Ultraviolet activator for polymerization | 2 |
| | 872.6350 | Ultraviolet detector | 2 |
| Dental Material | 872.3050 | Amalgam alloy | 2 |
| | 872.3060 | Gold-based alloys and precious metal alloys for clinical use | 2 |
| | 872.3200 | Resin tooth bonding agent | 2 |
| | 872.3250 | Calcium hydroxide cavity liner | 2 |
| | 872.3260 | Cavity varnish | 2 |
| | 872.3275 | Dental cement (other than zinc oxide-eugenol) | 2 |
| | 872.3300 | Hydrophilic resin coating for dentures | 2 |
| | 872.3310 | Coating material for resin fillings | 2 |
| | 872.3590 | Preformed plastic denture tooth | 2 |
| | 872.3660 | Impression material | 2 |
| | 872.3690 | Tooth shade resin material | 2 |
| | 872.3710 | Base metal alloy | 2 |
| | 872.3750 | Bracket adhesive resin and tooth conditioner | 2 |
| | 872.3760 | Denture relining, repairing, or rebasing resin | 2 |
| | 872.3765 | Pit and fissure sealant and conditioner | 2 |
| | 872.3770 | Temporary crown and bridge resin | 2 |

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 872.3820 | Root canal filling resin (other than chloroform use) | 2 |
| | 872.3920 | Porcelain tooth | 2 |
| Dental X-ray | 872.1800 | Extraoral source x-ray system | 2 |
| | 872.1810 | Intraoral source x-ray system | 2 |
| Dental Implants | 872.4880 | Intraosseous fixation screw or wire | 2 |
| | 872.3890 | Endodontic stabilizing splint | 2 |
| Orthodontic | 872.5470 | Orthodontic plastic bracket | 2 |
| *Ear/Nose/Throat Panel* | | | |
| Diagnostic Equipment | 874.1050 | Audiometer | 2 |
| | 874.1090 | Auditory impedance tester | 2 |
| | 874.1120 | Electronic noise generator for audiometric testing | 2 |
| | 874.1325 | Electroglottograph | 2 |
| | 874.1820 | Surgical nerve stimulator/locator | 2 |
| Hearing Aids | 874.3300 | Hearing aid (for bone-conduction) | 2 |
| | 874.3310 | Hearing aid calibrator and analysis system | 2 |
| | 874.3320 | Group hearing aid or group auditory trainer | 2 |
| | 874.3330 | Master hearing aid | 2 |
| Surgical Equipment | 874.4250 | Ear, nose, and throat electric or pneumatic surgical drill | 1 |
| | 874.4490 | Argon laser for otology, rhinology, and laryngology | 2 |
| | 874.4500 | Ear, nose, and throat microsurgical carbon dioxide laser | 2 |
| *Gastroenterology/Urology Panel* | | | |
| Endoscope (including angioscopes, laparscopes, ophthalmic endoscopes) | 876.1500 | Endoscope and accessories | 2 |
| | 876.4300 | Endoscopic electrosurgical unit and accessories | 2 |
| Gastroenterology | 876.1725 | Gastrointestinal motility monitoring system | 1 |
| Hemodialysis | 876.5600 | Sorbent regenerated dialysate delivery system for hemodialysis | 2 |
| | 876.5630 | Peritoneal dialysis system and accessories | 2 |
| | 876.5665 | Water purification system for hemodialysis | 2 |
| | 876.5820 | Hemodialysis system and accessories | 2 |
| | 876.5830 | Hemodialyzer with disposable insert (kiil-type) | 2 |
| Lithotriptor | 876.4500 | Mechanical lithotriptor | 2 |
| Urology Equipment | 876.1620 | Urodynamics measurement system | 2 |
| | 876.5320 | Nonimplanted electrical continence device | 2 |
| | 876.5880 | Isolated kidney perfusion and transport system and accessories | 2 |
| *General Hospital Panel* | | | |
| Infusion Pumps and Systems | 880.2420 | Electronic monitor for gravity flow infusion systems | 2 |
| | 880.2460 | Electrically powered spinal fluid pressure monitor | 2 |
| | 880.5430 | Nonelectrically powered fluid injector | 2 |
| | 880.5725 | Infusion pump | 2 |
| Neonatal Incubators | 880.5400 | Neonatal incubator | 2 |
| | 880.5410 | Neonatal transport incubator | 2 |
| | 880.5700 | Neonatal phototherapy unit | 2 |

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| Piston Syringes | 880.5570 | Hypodermic single lumen needle | 1 |
| | 880.5860 | Piston syringe (except antistick) | 1 |
| | 880.6920 | Syringe needle introducer | 2 |
| Miscellaneous | 880.2910 | Clinical electronic thermometer | 2 |
| | 880.2920 | Clinical mercury thermometer | 2 |
| | 880.5100 | AC-powered adjustable hospital bed | 1 |
| | 880.5500 | AC-powered patient lift | 2 |
| | 880.6880 | Steam sterilizer (greater than 2 cubic feet) | 2 |
| *Neurology Panel* | | | |
| | 882.1020 | Rigidity analyzer | 2 |
| | 882.1610 | Alpha monitor | 2 |
| Neuro-Diagnostic | 882.1320 | Cutaneous electrode | 2 |
| | 882.1340 | Nasopharyngeal electrode | 2 |
| | 882.1350 | Needle electrode | 2 |
| | 882.1400 | Electroencephalograph | 2 |
| | 882.1460 | Nystagmograph | 2 |
| | 882.1480 | Neurological endoscope | 2 |
| | 882.1540 | Galvanic skin response measurement device | 2 |
| | 882.1550 | Nerve conduction velocity measurement device | 2 |
| | 882.1560 | Skin potential measurement device | 2 |
| | 882.1570 | Powered direct-contact temperature measurement device | 2 |
| | 882.1620 | Intracranial pressure monitoring device | 2 |
| | 882.1835 | Physiological signal amplifier | 2 |
| | 882.1845 | Physiological signal conditioner | 2 |
| | 882.1855 | Electroencephalogram (EEG) telemetry system | 2 |
| | 882.5050 | Biofeedback device | 2 |
| Echoencephalography | 882.1240 | Echoencephalograph | 2 |
| RPG | 882.4400 | Radiofrequency lesion generator | 2 |
| Neuro Surgery | none | Electrode, spinal epidural | 2 |
| | 882.4305 | Powered compound cranial drills, burrs, trephines, and their accessories | 2 |
| | 882.4310 | Powered simple cranial drills burrs, trephines, and their accessories | 2 |
| | 882.4360 | Electric cranial drill motor | 2 |
| | 882.4370 | Pneumatic cranial drill motor | 2 |
| | 882.4560 | Stereotaxic instrument | 2 |
| | 882.4725 | Radiofrequency lesion probe | 2 |
| | 882.4845 | Powered rongeur | 2 |
| | 882.5500 | Lesion temperature monitor | 2 |
| Stimulators | 882.1870 | Evoked response electrical stimulator | 2 |
| | 882.1880 | Evoked response mechanical stimulator | 2 |
| | 882.1890 | Evoked response photic stimulator | 2 |
| | 882.1900 | Evoked response auditory stimulator | 2 |
| | 882.1950 | Tremor transducer | 2 |
| | 882.5890 | Transcutaneous electrical nerve stimulator for pain relief | 2 |

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| *Obstetrics/Gynecology Panel* | | | |
| Fetal Monitoring | 884.1660 | Transcervical endoscope (amnioscope) and accessories | 2 |
| | 884.1690 | Hysteroscope and accessories (for performance standards) | 2 |
| | 884.2225 | Obstetric-gynecologic ultrasonic imager | 2 |
| | 884.2600 | Fetal cardiac monitor | 2 |
| | 884.2640 | Fetal phonocardiographic monitor and accessories | 2 |
| | 884.2660 | Fetal ultrasonic monitor and accessories | 2 |
| | 884.2675 | Fetal scalp circular (spiral) electrode and applicator | 1 |
| | 884.2700 | Intrauterine pressure monitor and accessories | 2 |
| | 884.2720 | External uterine contraction monitor and accessories | 2 |
| | 884.2740 | Perinatal monitoring system and accessories | 2 |
| | 884.2960 | Obstetric ultrasonic transducer and accessories | 2 |
| Gynecological Surgery Equipment | 884.1720 | Gynecologic laparoscope and accessories | 2 |
| | 884.4160 | Unipolar endoscopic coagulator-cutter and accessories | 2 |
| | 884.4550 | Gynecologic surgical laser | 2 |
| | 884.4120 | Gynecologic electrocautery and accessories | 2 |
| | 884.5300 | Condom | 2 |
| Ophthalmic Implants | 886.3320 | Eye sphere implant | 2 |
| Contact Lens | 886.1385 | Polymethylmethacrylate (PMMA) diagnostic contact lens | 2 |
| | 886.5916 | Rigid gas permeable contact lens (daily wear only) | 2 |
| Diagnostic Equipment | 886.1120 | Opthalmic camera | 1 |
| | 886.1220 | Corneal electrode | 1 |
| | 886.1250 | Euthyscope (AC-powered) | 1 |
| | 886.1360 | Visual field laser instrument | 1 |
| | 886.1510 | Eye movement monitor | 1 |
| | 886.1570 | Ophthalmoscope | 1 |
| | 886.1630 | AC-powered photostimulator | 1 |
| | 886.1640 | Ophthalmic preamplifier | 1 |
| | 886.1670 | Ophthalmic isotope uptake probe | 2 |
| | 886.1780 | Retinoscope (AC-powered device) | 1 |
| | 886.1850 | AC-powered slit lamp biomicroscope | 1 |
| | 886.1930 | Tonometer and accessories | 2 |
| | 886.1945 | Transilluminator (AC-powered device) | 1 |
| | 886.3130 | Ophthalmic conformer | 2 |
| (Diagnostic/Surgery Equipment) | 886.4670 | Phacofragmentation system | 2 |
| Ophthalmic Implants | 886.3340 | Extraocular orbital implant | 2 |
| | 886.3800 | Scleral shell | 2 |
| Surgical Equipment | 880.5725 | Infusion pump (performance standards) | 2 |
| | 886.3100 | Ophthalmic tantalum clip | 2 |
| | 886.3300 | Absorbable implant (scleral buckling method) | 2 |
| | 886.4100 | Radiofrequency electrosurgical cautery apparatus | 2 |
| | 886.4115 | Thermal cautery unit | 2 |
| | 886.4150 | Vitreous aspiration and cutting instrument | 2 |

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 886.4170 | Cryophthalmic unit | 2 |
| | 886.4250 | Ophthalmic electrolysis unit (AC-powered device) | 1 |
| | 886.4335 | Operating headlamp (AC-powered device) | 1 |
| | 886.4390 | Ophthalmic laser | 2 |
| | 886.4392 | Nd:YAG laser for posterior capsulotomy | 2 |
| | 886.4400 | Electronic metal locator | 1 |
| | 886.4440 | AC-powered magnet | 1 |
| | 886.4610 | Ocular pressure applicator | 2 |
| | 886.4690 | Ophthalmic photocoagulator | 2 |
| | 886.4790 | Ophthalmic sponge | 2 |
| | 886.5100 | Ophthalmic beta radiation source | 2 |
| | none | Ophthalmoscopes, replacement batteries, hand-held | 1 |
| *Orthopedic Panel* | | | |
| Implants | 888.3010 | Bone fixation cerclage | 2 |
| | 888.3020 | Intramedullary fixation rod | 2 |
| | 888.3030 | Single/multiple component metallic bone fixation appliances and accessories | 2 |
| | 888.3040 | Smooth or threaded metallic bone fixation fastener | 2 |
| | 888.3050 | Spinal interlaminal fixation orthosis | 2 |
| | 888.3060 | Spinal intervertebral body fixation orthosis | 2 |
| Surgical Equipment | 888.1240 | AC-powered dynamometer | 2 |
| | 888.4580 | Sonic surgical instrument and accessories/attachments | 2 |
| | none | Accessories, fixation, spinal interlaminal | 2 |
| | none | Accessories, fixation, spinal intervertebral body | 2 |
| | none | Monitor, pressure, intracompartmental | 1 |
| | none | Orthosis, fixation, spinal intervertebral fusion | 2 |
| | none | Orthosis, spinal pedicle fixation | |
| | none | System, cement removal extraction | 1 |
| *Physical Medicine Panel* | | | |
| Diagnostic Equipment or (Therapy) Therapeutic Equipment | 890.1225 | Chronaximeter | 2 |
| | 890.1375 | Diagnostic electromyograph | 2 |
| | 890.1385 | Diagnostic electromyograph needle electrode | 2 |
| | 890.1450 | Powered reflex hammer | 2 |
| | 890.1850 | Diagnostic muscle stimulator | 2 |
| or (Therapy) | 890.5850 | Powered muscle stimulator | 2 |
| Therapeutic Equipment | 890.5100 | Immersion hydrobath | 2 |
| | 890.5110 | Paraffin bath | 2 |
| | 890.5500 | Infrared lamp | 2 |
| | 890.5720 | Water circulating hot or cold pack | 2 |
| | 890.5740 | Powered heating pad | 2 |
| *Radiology Panel* | | | |
| MRI | 892.1000 | Magnetic resonance diagnostic device | 2 |
| Ultrasound Diagnostic | 884.2660 | Fetal ultrasonic monitor and accessories | 2 |
| | 892.1540 | Nonfetal ultrasonic monitor | |
| | 892.1560 | Ultrasonic pulsed echo imaging system | 2 |
| | 892.1570 | Diagnostic ultrasonic transducer | 2 |

TABLE 3—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 892.1550 | Ultrasonic pulsed doppler imaging system | |
| Angiographic | 892.1600 | Angiographic x-ray system | 2 |
| Diagnostic X-Ray | 892.1610 | Diagnostic x-ray beam-limiting device | 2 |
| | 892.1620 | Cine or spot fluorographic x-ray camera | 2 |
| | 892.1630 | Electrostatic x-ray imaging system | 2 |
| | 892.1650 | Image-intensified fluoroscopic x-ray system | 2 |
| | 892.1670 | Spot film device | 2 |
| | 892.1680 | Stationary x-ray system | 2 |
| | 892.1710 | Mammographic x-ray system | 2 |
| | 892.1720 | Mobile x-ray system | 2 |
| | 892.1740 | Tomographic x-ray system | 1 |
| | 892.1820 | Pneumoencephalographic chair | 2 |
| | 892.1850 | Radiographic film cassette | 1 |
| | 892.1860 | Radiographic film/cassette changer | 1 |
| | 892.1870 | Radiographic film/cassette changer programmer | 2 |
| | 892.1900 | Automatic radiographic film processor | 2 |
| | 892.1980 | Radiologic table | 1 |
| CT Scanner | 892.1750 | Computed tomography x-ray system | 2 |
| Radiation Therapy | 892.5050 | Medical charged-particle radiation therapy system | 2 |
| | 892.5300 | Medical neutron radiation therapy system | 2 |
| | 892.5700 | Remote controlled radionuclide applicator system | 2 |
| | 892.5710 | Radiation therapy beam-shaping block | 2 |
| | 892.5730 | Radionuclide brachytherapy source | 2 |
| | 892.5750 | Radionuclide radiation therapy system | 2 |
| | 892.5770 | Powered radiation therapy patient support assembly | 2 |
| | 892.5840 | Radiation therapy simulation system | 2 |
| | 892.5930 | Therapeutic x-ray tube housing assembly | 1 |
| Nuclear Medicine | 892.1170 | Bone densitometer | 2 |
| | 892.1200 | Emission computed tomography system | 2 |
| | 892.1310 | Nuclear tomography system | 1 |
| | 892.1390 | Radionuclide rebreathing system | 2 |
| General/Plastic Surgery Panel | | | |
| Surgical Lamps | 878.4630 | Ultraviolet lamp for dermatologic disorders | 2 |
| | 890.5500 | Infrared lamp | 2 |
| | 878.4580 | Surgical lamp | 2 |
| Electrosurgical Cutting Equipment | 878.4810 | Laser surgical instrument for use in general and plastic surgery and in dermatology | 2 |
| | 878.4400 | Electrosurgical cutting and coagulation device and accessories | 2 |
| Miscellaneous | 878.4780 | Powered suction pump | 2 |

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at http://www.fda.gov/cdrh/prodcode.html.

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

APPENDIXES C–F TO SUBPART B OF PART 26 [RESERVED]

## Subpart C—''Framework'' Provisions

### § 26.60 Definitions.

(a) The following terms and definitions shall apply to this subpart only:

(1) *Designating Authority* means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this part.

(2) *Designation* means the identification by a designating authority of a conformity assessment body to perform conformity assessment procedures under this part.

(3) *Regulatory Authority* means a government agency or entity that exercises a legal right to control the use or sale of products within a party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

(b) Other terms concerning conformity assessment used in this part shall have the meaning given elsewhere in this part or in the definitions contained in ''Guide 2: Standardization and Related Activities—General Vocabulary of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC)'' (ISO/IEC Guide 2) (1996 edition), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the International Organization for Standardization, 1, rue de Varembé, Case postale 56, CH–1211 Genève 20, Switzerland, or on the Internet at http://www.iso.ch or may be examined at the Food and Drug Administration's Medical Library, 5600 Fishers Lane, rm. 11B–40, Rockville, MD 20857, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. In the event of an inconsistency between the ISO/IEC Guide 2 and definitions in this part, the definitions in this part shall prevail.

### § 26.61 Purpose of this part.

This part specifies the conditions by which each party will accept or recognize results of conformity assessment procedures, produced by the other party's conformity assessment bodies (CAB's) or authorities, in assessing conformity to the importing party's requirements, as specified on a sector-specific basis in subparts A and B of this part, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the parties with regard to conformity assessment for all products covered under this part. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the party alleging its market access has been denied may, within 90 days of such consultation, invoke its right to terminate the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, in accordance with § 26.80.

### § 26.62 General obligations.

(a) The United States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other party's conformity assessment bodies (CAB's) and/or authorities.

(b) The European Community (EC) and its Member States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the EC and its Member States, produced by the other party's CAB's and/or authorities.

(c) Where sectoral transition arrangements have been specified in subparts A and B of this part, the obligations in paragraphs (a) and (b) of this

section will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure conformity to the satisfaction of the receiving party, with applicable legislative, regulatory, and administrative provisions of that party, equivalent to the assurance offered by the receiving party's own procedures.

### § 26.63 General coverage of this part.

(a) This part applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this part.

(b) Subparts A and B of this part may include:

(1) A description of the relevant legislative, regulatory, and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(2) A statement on the product scope and coverage;

(3) A list of designating authorities;

(4) A list of agreed conformity assessment bodies (CAB's) or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(5) The procedures and criteria for designating the CAB's;

(6) A description of the mutual recognition obligations;

(7) A sectoral transition arrangement;

(8) The identity of a sectoral contact point in each party's territory; and

(9) A statement regarding the establishment of a Joint Sectoral Committee.

(c) This part shall not be construed to entail mutual acceptance of standards or technical regulations of the parties and, unless otherwise specified in subpart A or B of this part, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

### § 26.64 Transitional arrangements.

The parties agree to implement the transitional commitments on confidence building as specified in subparts A and B of this part.

(a) The parties agree that each sectoral transitional arrangement shall specify a time period for completion.

(b) The parties may amend any transitional arrangement by mutual agreement.

(c) Passage from the transitional phase to the operational phase shall proceed as specified in subparts A and B of this part, unless either party documents that the conditions provided in such subpart for a successful transition are not met.

### § 26.65 Designating authorities.

The parties shall ensure that the designating authorities specified in subpart B of this part have the power and competence in their respective territories to carry out decisions under this part to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies (CAB's).

### § 26.66 Designation and listing procedures.

The following procedures shall apply with regard to the designation of conformity assessment bodies (CAB's) and the inclusion of such bodies in the list of CAB's in subpart B of this part:

(a) The designating authority identified in subpart B of this part shall designate CAB's in accordance with the procedures and criteria set forth in subpart B of this part;

(b) A party proposing to add a CAB to the list of such bodies in subpart B of this part shall forward its proposal of one or more designated CAB's in writing to the other party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in subpart B of this part of the proposed CAB or CAB's shall take effect; and

(d) In the event that the other party contests on the basis of documented evidence the technical competence or compliance of a proposed CAB, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such CAB shall not be included on the list of CAB's in subpart

B of this part. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the CAB in subpart B may be resubmitted to the other party.

### § 26.67 Suspension of listed conformity assessment bodies.

The following procedures shall apply with regard to the suspension of a conformity assessment body (CAB) listed in subpart B of this part.

(a) A party shall notify the other party of its contestation of the technical competence or compliance of a CAB listed in subpart B of this part and the contesting party's intent to suspend such CAB. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other party;

(b) The CAB shall be given prompt notice by the other party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) Any such contestation shall be discussed between the parties in the Joint Sectoral Committee described in subpart B of this part. If there is no Joint Sectoral Committee, the contesting party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the CAB shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the party in whose territory the body in question is located, but may be carried out jointly by the parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the CAB shall be suspended upon the request of the contesting party;

(f) Upon the suspension of a CAB listed in subpart B of this part, a party is no longer obligated to accept or recognize the results of conformity assessment procedures performed by that CAB subsequent to suspension. A party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to suspension, unless a regulatory authority of the party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part; and

(g) The suspension shall remain in effect until agreement has been reached by the parties upon the future status of that body.

### § 26.68 Withdrawal of listed conformity assessment bodies.

The following procedures shall apply with regard to the withdrawal from subpart B of this part of a conformity assessment body (CAB):

(a) A party proposing to withdraw a CAB listed in subpart B of this part shall forward its proposal in writing to the other party;

(b) Such CAB shall be promptly notified by the other party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the withdrawal from the list in subpart B of this part of the CAB shall take effect;

(d) In the event the other party opposes the proposal to withdraw by supporting the technical competence and compliance of the CAB, the CAB shall not at that time be withdrawn from the list of CAB's in subpart B of this part. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such

verification, the proposal for withdrawal of the CAB may be resubmitted to the other party; and

(e) Subsequent to the withdrawal of a CAB listed in subpart B of this part, a party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to withdrawal, unless a regulatory authority of the party decides otherwise based on health, safety, and environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part.

### § 26.69 Monitoring of conformity assessment bodies.

The following shall apply with regard to the monitoring of conformity assessment bodies (CAB's) listed in subpart B of this part:

(a) Designating authorities shall assure that their CAB's listed in subpart B of this part are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in subpart B of this part. In this regard, designating authorities shall maintain, or cause to maintain, ongoing surveillance over their CAB's by means of regular audit or assessment;

(b) The parties undertake to compare methods used to verify that the CAB's listed in subpart B of this part comply with the relevant requirements of subpart B of this part. Existing systems for the evaluation of CAB's may be used as part of such comparison procedures;

(c) Designating authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both parties, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of CAB's listed in subpart B of this part; and

(d) Designating authorities shall consult, as necessary, with the relevant regulatory authorities of the other party to ensure that all technical requirements are identified and are satisfactorily addressed.

### § 26.70 Conformity assessment bodies.

Each party recognizes that the conformity assessment bodies (CAB's) listed in subpart B of this part fulfill the conditions of eligibility to assess conformity in relation to its requirements as specified in subpart B of this part. The parties shall specify the scope of the conformity assessment procedures for which such bodies are listed.

### § 26.71 Exchange of information.

(a) The parties shall exchange information concerning the implementation of the legislative, regulatory, and administrative provisions identified in subparts A and B of this part.

(b) Each party shall notify the other party of legislative, regulatory, and administrative changes related to the subject matter of this part at least 60 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a party shall notify the other party as soon as practicable.

(c) Each party shall promptly notify the other party of any changes to its designating authorities and/or conformity assessment bodies (CAB's).

(d) The parties shall exchange information concerning the procedures used to ensure that the listed CAB's under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in subpart B of this part.

(e) Regulatory authorities identified in subparts A and B of this part shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

### § 26.72 Sectoral contact points.

Each party shall appoint and confirm in writing contact points to be responsible for activities under subparts A and B of this part.

### § 26.73 Joint Committee.

(a) A Joint Committee consisting of representatives of the United States and the European Community (EC) will be established. The Joint Committee

shall be responsible for the effective functioning of the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived.

(b) The Joint Committee may establish Joint Sectoral Committees comprised of appropriate regulatory authorities and others deemed necessary.

(c) The United States and the EC shall each have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.

(d) The Joint Committee may consider any matter relating to the effective functioning of that agreement. In particular it shall be responsible for:

(1) Listing, suspension, withdrawal and verification of conformity assessment bodies (CAB's) in accordance with that agreement;

(2) Amending transitional arrangements in the sectoral annexes to that agreement;

(3) Resolving any questions relating to the application of that agreement not otherwise resolved in the respective Joint Sectoral Committees;

(4) Providing a forum for discussion of issues that may arise concerning the implementation of that agreement;

(5) Considering ways to enhance the operation of that agreement;

(6) Coordinating the negotiation of additional sectoral annexes to that agreement; and

(7) Considering whether to amend that agreement in accordance with § 26.80.

(e) When a party introduces new or additional conformity assessment procedures affecting a sectoral annex to that agreement, the parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of that agreement and the relevant sectoral annex.

### § 26.74 Preservation of regulatory authority.

(a) Nothing in this part shall be construed to limit the authority of a party to determine, through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable subpart A or B of this part.

(b) Nothing in this part shall be construed to limit the authority of a regulatory authority to take all appropriate and immediate measures whenever it ascertains that a product may:

(1) Compromise the health or safety of persons in its territory;

(2) Not meet the legislative, regulatory, or administrative provisions within the scope of the applicable subpart A or B of this part; or

(3) Otherwise fail to satisfy a requirement within the scope of the applicable subpart A or B of this part. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the regulatory authority takes such action, it shall inform its counterpart authority and the other party within 15 days of taking such action, providing its reasons.

### § 26.75 Suspension of recognition obligations.

Either party may suspend its obligations under subpart A or B of this part, in whole or in part, if:

(a) A party suffers a loss of market access for the party's products within the scope of subpart A or B of this part as a result of the failure of the other party to fulfill its obligations under this part;

(b) The adoption of new or additional conformity assessment requirements as referenced in § 26.73(e) results in a loss of market access for the party's products within the scope of subpart B of this part because conformity assessment bodies (CAB's) designated by the party in order to meet such requirements have not been recognized by the party implementing the requirements; or

(c) The other party fails to maintain legal and regulatory authorities capable of implementing the provisions of this part.

### § 26.76 Confidentiality.

(a) Each party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this part.

(b) In particular, neither party shall disclose to the public, nor permit a conformity assessment body (CAB) to disclose to the public, information exchanged under this part that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

(c) A party or a CAB may, upon exchanging information with the other party or with a CAB of the other party, designate the portions of the information that it considers to be exempt from disclosure.

(d) Each party shall take all precautions reasonably necessary to protect information exchanged under this part from unauthorized disclosure.

### § 26.77 Fees.

Each party shall endeavor to ensure that fees imposed for services under this part shall be commensurate with the services provided. Each party shall ensure that, for the sectors and conformity assessment procedures covered under this part, it shall charge no fees with respect to conformity assessment services provided by the other party.

### § 26.78 Agreements with other countries.

Except where there is written agreement between the parties, obligations contained in mutual recognition agreements concluded by either party with a party not a party to the agreement from which this part is derived (a third party) shall have no force and effect with regard to the other party in terms of acceptance of the results of conformity assessment procedures in the third party.

### § 26.79 Territorial application.

The agreement from which this part is derived shall apply, on the one hand, to the territories in which the Treaty establishing the European Community (EC) is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of the United States.

### § 26.80 Entry into force, amendment, and termination.

(a) The ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, including its sectoral annexes on telecommunication equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical Good Manufacturing Practices (GMP) inspections, and medical devices shall enter into force on the first day of the second month following the date on which the parties have exchanged letters confirming the completion of their respective procedures for the entry into force of that agreement.

(b) That agreement including any sectoral annex may, through the Joint Committee, be amended in writing by the parties to that agreement. Those parties may add a sectoral annex upon the exchange of letters. Such annex shall enter into force 30 days following the date on which those parties have exchanged letters confirming the completion of their respective procedures for the entry into force of the sectoral annex.

(c) Either party to that agreement may terminate that agreement in its entirety or any individual sectoral annex thereof by giving the other party to that agreement 6-months notice in writing. In the case of termination of one or more sectoral annexes, the parties to that agreement will seek to achieve by consensus to amend that agreement, with a view to preserving the remaining Sectoral Annexes, in accordance with the procedures in this section. Failing such consensus, that agreement shall terminate at the end of 6 months from the date of notice.

(d) Following termination of that agreement in its entirety or any individual sectoral annex thereof, a party to that agreement shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under that agreement prior to termination, unless a regulatory authority in the party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable sectoral annex.

**§ 26.81 Final provisions.**

(a) The sectoral annexes referred to in § 26.80(a), as well as any new sectoral annexes added pursuant to § 26.80(b), shall form an integral part of the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived.

(b) For a given product or sector, the provisions contained in subparts A and B of this part shall apply in the first place, and the provisions of subpart C of this part in addition to those provisions. In the case of any inconsistency between the provisions of subpart A or B of this part and subpart C of this part, subpart A or B shall prevail, to the extent of that inconsistency.

(c) The agreement from which this part is derived shall not affect the rights and obligations of the parties under any other international agreement.

(d) In the case of subpart B of this part, the parties shall review the status of such subpart at the end of 3 years from the date described in § 26.80(a).

# PART 50—PROTECTION OF HUMAN SUBJECTS

## Subpart A—General Provisions



## Subpart B—Informed Consent of Human Subjects



## Subpart C [Reserved]

## Subpart D—Additional Safeguards for Children in Clinical Investigations



AUTHORITY: 21 U.S.C 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

SOURCE: 45 FR 36390, May 30, 1980, unless otherwise noted.

## Subpart A—General Provisions

**§ 50.1 Scope.**

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal